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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|----------------------|-----------------------------|------------------|
| 10/712,063 | 11/14/2003 | Hugh R. Sharkey | 14170-038004 | 9046 |
| Joel R. Petrow, Esq. Smith & Nephew, Inc. | | | EXAMINER PEFFLEY, MICHAEL F | |
| | | | | |
| | | 3739 | | |
| SHORTENED STATUTOR | HORTENED STATUTORY PERIOD OF RESPONSE MAIL DATE | | DELIVERY MODE | |
| · 3 MO | · 3 MONTHS | | DADED | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| | Application No. | Applicant(s) | | | | | | | | | | |
|---|---|--------------------------------|--|--|--|--|---|--|--|--|--|--|
| Office Action Summan | 10/712,063 | SHARKEY ET AL. | | | | | | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | | | | | | |
| | Michael Peffley | 3739 | | | | | | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum standurory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | | | | | |
| Status | | | | | | | | | | | | |
| 1) Responsive to communication(s) filed on 14 No | ovember 2003. | | | | | | | | | | | |
| | <u> </u> | | | | | | | | | | | |
| <i>,</i> |) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | | | | | | |
| Disposition of Claims | | | | | | | | | | | | |
| 4)⊠ Claim(s) <u>1-28</u> is/are pending in the application. | | | | | | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | | | | | |
| 6)⊠ Claim(s) <u>1-28</u> is/are rejected. | | | | | | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | | | | | | | |
| Application Papers | | | | | | | | | | | | |
| 9)⊠ The specification is objected to by the Examine | r. | | | | | | | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | epted or b) objected to by the E | Examiner. | | | | | | | | | | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | | | | | | | | |
| Replacement drawing sheet(s) including the correct | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | | | | | | |
| Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | | | | | |
| | | | | | | • • | application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| | | | | | | * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | | | | | | | |
| Attachment(s) | | | | | | | | | | | | |
| Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | | | | | | | |
| 2) | Paper No(s)/Mail Da 5) Notice of Informal P | | | | | | | | | | | |
| Paper No(s)/Mail Date <u>11/14/03</u> ; <u>3/31/04</u> ; <u>10/27/04</u> . | | | | | | | | | | | | |

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Specification

The disclosure is objected to because of the following informalities: the "Cross Reference to Related Applications" section should be updated to provide the most current status (i.e. US Patent Number) for the related applications.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,980,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims set forth the same general steps with only minor, obvious differences in the steps. For example, claim 1 of the instant application recites steps of inserting an introducer and a catheter into an intervertebral disc, advancing a distal region of the catheter through the nucleus pulposus by blunt dissection, delivering RF energy and removing material to reduce pressure in the disc. The patented claims recite a more specific catheter in claim 1, and include the steps of introducing the catheter into the intervertebral disc using an introducer (claim 3) and with blunt dissection ("positioning" step of claim 1). The patented claims also include the steps of removing material with a functional element (claim 6), but fail to specify the use of RF energy. The use of RF energy as the functional element delivery means is deemed to be an obvious consideration for one of ordinary skill in the art, particularly since the '504 patent is directed specifically to the RF treatment of disc tissue.

Claims 1-28 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,126,682.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims set forth the same general steps with only minor, obvious differences in the steps. For example, the patented claims recite a more

specific catheter in claim 1, and include the steps of introducing the catheter into the intervertebral disc with blunt dissection ("positioning" step of claim 1). The patented claims also include the steps of removing material with a functional element (claim 6), but fail to specify the use of RF energy. The use of RF energy as the functional element delivery means is deemed to be an obvious consideration for one of ordinary skill in the art, particularly since the '504 patent is directed specifically to the RF treatment of disc tissue. Also, the use of an introducer (e.g. a needle) in the patented '504 steps would be deemed an obvious means for providing the device within the disc as is generally known in the art.

Claims 1-28 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,290,715.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims set forth the same general steps with only minor, obvious differences in the steps. For example, the patented claims recite a more specific catheter in claim 1, and include the steps of introducing the catheter into the intervertebral disc using with blunt dissection (claim 27). The patented claims also include the steps of removing material with a functional element (claim 6), but fail to specify the use of RF energy (although "electromagnetic energy" is set forth). The use of RF energy as the functional element delivery means is deemed to be an obvious form of electromagnetic energy for one of ordinary skill in the art, particularly since the '504 patent is directed specifically to the RF treatment of disc tissue. And the use of an

introducer (e.g. a needle) is deemed to be an obvious means for providing the device within the disc.

Claims 1-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/712,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims set forth the same general steps with only minor, obvious differences in the steps.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/712,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims set forth the same general steps with only minor, obvious differences in the steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sluijter et al (5,433,739) remains the most relevant prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Perfley Primary Examine Art Unit 3739

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December 14, 2006